

EXHIBIT AA

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Dr. A. J. Melveger

cc: Dr. S. Garg
Dr. R. Kronenthal
Dr. A. Levy
Mr. R. Lilenfeld
Dr. J. McDivitt
Mr. R. Morrissey
Mr. F. Schiller
RDCF

IR MICROSCOPY OF EXPLANTED PROLENE*
RECEIVED FROM PROF. R. GUIDOIN

Samples of PROLENE* suture carefully removed from human vascular graft explants received from Prof. R. Guidoin were examined by IR microscopy "as is". A PROLENE suture control was examined for comparison. The samples are described below:

<u>Sample</u>	<u>Implant Duration</u>	<u>Microscopy Observations (SEM- F. Schiller)</u>	<u>IR Spectra (Figure #)</u>
83D062 + 83TI9020	2 yr.	No cracking	1,2
83D035	8 yr.	Severe cracking	3,4,5,6,7
TB2418-Q Sterile Product	Non-implanted control	--	8,9

The samples were examined "as is" with no special preparation. Multiple spectra were obtained at different sites along the explants, especially for the 8-year severely cracked specimens. The IR spectra appear "bottomed out" since the sample thickness is quite significant.

Some samples of 83D035 (8 yr.) were examined optically. Using a needle, the cracked surfaces were easily wiped off and deposited on a KBr window. The surface "scrapings" had the handling and consistency of a waxy snow. The sample was not conducive to IR microscopy in this form however. Similar treatment with needles on sterile packaged PROLENE and the 2-year sample generated no scrapings.

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The surface scrapings of 83D035 were melted at 147°-156°C on the Mettler hot stage. This is the melting range previously observed for oxidatively degraded polypropylene. IR microscopy of the melted film produced (Figures 10 & 11) yielded good spectra.

Observations

Spectra of samples examined "as is" show remarkable similarity between explanted suture and unimplanted suture. All major polypropylene and pigment bands are observed (Figure 9). The 1740 cm^{-1} band, seen strongest in the sterile product, is due to dilauryl thiodipropionate (DLTDP) additive. The DLTDP appears reduced in the 2-year sample spectra and further reduced in the 8-year sample spectra. DLTDP is not observed in the surface scraping spectra.

The observation of chemical species in the surface scrapings spectra of 83D035, yet not seen in the "bulk" spectra (surface + interior) of the suture explants, suggests that the regions affected by cracking or degradation are very small relative to the entire suture. The surface scraping spectra are very different from the "bulk" spectra, and both types of spectra show no evidence of the presence of protein.

The surface scrapings spectra of 83D035 clearly indicate polypropylene, but also three or four other broadened bands. Table I explains the possible functionalities determined from a library search of the IR bands not normally seen in polypropylene.

Conclusions

The IR data collected for the PROLENE suture explant samples suggest:

1. The amount of DLTDP is reduced in the explanted sutures. No DLTDP is observed in the surface scraped (cracked regions) of 83D035. The observed DLTDP decreases with implant time.
2. No protein is observed in any spectra of the explanted sutures.
3. The surface scraped material from the cracked regions of 83D035 has a melting range indicative of degraded polypropylene. The IR spectra of this scraped material is clearly polypropylene, but it appears to be degraded in an oxidative fashion. There are a number of degradation species possible from the IR data. Hydroxyl and acid/ester functionality are definitely present. Ketone and/or unsaturated species are suggested, but not verified.
4. The degraded portion of the 8-year explant makes up only a minor portion of the entire suture.


D. F. Burkley

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Attachment
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